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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,622	12/21/2000	Curtis Cole	JBP-534	7817

7590 09/30/2002

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EXAMINER
YU, GINA C

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/30/2002 15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/742,622	COLE ET AL.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 22, 2002 has been entered. Claims 1-23 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 11, 13, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfirramann et al. (GB 1182320) ("Pfirramann").

The broadest claims of the instant application claim method of using composition comprising pharmaceutically acceptable acid salts of at least one amine selected from a specified group of amines.

Pfirramann discloses topical composition comprising the dimethylaminoethanol salt of dihydrooratic acid. See Example 4 and 7. The claimed methods of improving "the firmness of skin", "the appearance of facial contours", and "reducing the

appearance of sagging skin" are necessarily practiced when the Pfirramann composition topically applied as taught by the reference.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-6, 9, 11, 13-17, 20, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 4197316). ("Yu").

Yu discloses a method to treat dry skin, including facial skin, using topical composition which comprise one or more alpha hydroxy acids, esters thereof, and their ammonium salts. See abstract; col. 1, lines 16 – 40. See instant claims 1, 2, 3, 13, 14, and 23. Compositions containing ethanolamine salt of glycolic acid, and triethanolamine salt of lactic acid are disclosed. See Examples 1-5. The pH of the solutions in the example range from 4.4 to 4.7, while the reference generally teaches that the pH of the final composition may range from 3.5-7.5. See instant claims 9 and 20. The reference teaches that secondary amines such as N-methylethanolamine and N-ethylethanolamine. See col. 3, lines 14 – 25. A solution containing 2 grams of glycolic acid, 2 grams of citric acid, and ethanolamine is disclosed in Example 5. See instant claims 4-6, 14-17. Using malice acid is also suggested. See col. 1, line 60; col. 3, line 30.

While Yu fails to disclose specific example of formulating composition with the salt of the recited limitations in instant claim 1, the reference teaches that N-ethylethanolamine is a suitable secondary amine for the invention. It would have been

obvious to one of ordinary skill in the art at the time the invention was made to have modified the illustrated examples of the Yu reference by substituting the amine salts there with other suitable components such as the salt of N-ethylethanolamine, as suggested by the reference, because of the expectation of successfully producing a skin treatment composition with similar effectiveness. Examiner further takes the view that the claimed methods of improving "the firmness of skin", "the appearance of facial contours", and "reducing the appearance of sagging skin" are necessarily practiced by topically applying the obvious variation of the prior art composition.

2. Claims 7, 8, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claim 1-6, 9, 11, 13-17, 20, 22, and 23 above, and further in view of Znaiden (US 5523090).

While Yu, discussed above, teaches malic acid may be used, the reference fails to teach the specific weight ratio of the malic acid and glycolic acid.

Znaiden discloses skin treatment compositions for improving skin strength and firmness, which comprise salts of alpha hydroxy acids and caffeine. While a composition containing 1:1 weight ratio of malic acid and lactic acid is disclosed in example 12, the reference fails to teach the specific example of combining malic acid and glycolic acid. The reference, however, teaches that the most preferred acids in the invention include glycolic acid and lactic, and the reference further teaches that the choice of these alpha hydroxy acid depends on the efficacy of compositions in increasing percutaneous absorption. See col. 5, lines 43 – 45.

In general, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is *critical*. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Yu and Znaiden, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the Yu invention by optimizing the weight ratio of the preferred alpha-hydroxy acids, such as malic acid and glycolic acid, as motivated by Znaiden, for desired absorption level of the compositions

3. Claims 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu and Znaiden as applied to claim 1-9, 11, 13-20, 22, and 23 above, and further in view of Perricone (US 5554647).

While Yu, discussed above, discloses tertiary amine suitable for the invention, the reference fails to teach dimethylaminoethanol.

Znaiden, also discussed above, teaches that the presence of the salt would depend on the pH of the solution, and discloses solutions with pH of 5.5 or less. See col. 5, lines 35 – 48; Example 3.

Perricone teaches topical composition comprising dimethylaminoethanol in a dermatologically acceptable carrier for treating aging skin and muscles. See abstract; col. 3, line 36 – col. 4, line 5.

While the Perricone reference fails to teach salt of the dimethylaminoethanol with alphahydroxy acids, examiner views that the instant claims 10 and 21 are obvious in view of the combined references. It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two conventional skin care agents and the salt formed by the combination thereof when the pH is low. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerkhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have one of ordinary skill in the art at the time the invention was made to have modified the Yu, by adding dimethylethanolamine as motivated by Perricone, because of the expectation of successfully producing skin care composition to treat aging skin. Examiner views that the claimed methods are necessarily practiced when the obvious variation of the prior arts is topically applied to skin according to the disclosure.

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-6, 9, 11, 13-17, 20, 22, and 23 above, and further in view of Quan et al (U.S. Pat. No. 6,180,133 B1) ("Quan").

Yu fails to teach using the composition with the articles as required by claim 12.

Quan teaches an adhesive, matrix-patch for treating wrinkle. The adhesive contains mixture of vitamins, alpha hydroxy acids or their salts, and glycerine. See col. 3, line 45 – col. 4, line 63; col. 4, lines 44 – col. 5, line 23. The reference teaches that the administration of the composition with the patch system is more effective than by hand, and provides the enhanced absorption of the therapeutic components into the skin. See col. 7, lines 7 – 35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of the Yu reference by incorporating the compositions into an adhesive patch, as motivated by Quan, because of expectation to have successfully administered the therapeutic components in the combined references more effectively.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, and 13-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2,

4-7,10 –12, and 14-16 of copending Application No. 09/777,737. Although the conflicting claims are not identical, both claims are directed to skin care compositions comprising alpha hydroxy acids or salts thereof and overlapping ranges of akanolamines.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
September 27, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER

9/28/02